



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

Address: COMMISSIONER FOR PATENTS

P.O. Box 1450

Alexandria, Virginia 22313-1450

www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/534,538	10/31/2005	Yongzhi Xi	272331US0PCT	7166
22850	7590	08/27/2010		
OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, L.L.P. 1940 DUKE STREET ALEXANDRIA, VA 22314				
EXAMINER				
LONG, SCOTT				
ART UNIT		PAPER NUMBER		
1633				
NOTIFICATION DATE		DELIVERY MODE		
08/27/2010		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentdocket@oblon.com

oblonpat@oblon.com

jgardner@oblon.com

Office Action Summary

Application No.

10/534,538

Applicant(s)

XI ET AL.

Examiner

SCOTT LONG

Art Unit

1633

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 August 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 12, 13 and 15-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 12, 13 and 15-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB-08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

The examiner acknowledges receipt of Applicant's Remarks and Claim amendments, filed on 17 August 2010.

Claim Status

Claims 1-11, 14, and 18-21 are canceled. Claims 12-13 and 17 are amended. Claims 12-13 and 15-17 are under current examination.

Priority

This application claims benefit as a 371 of PCT/CN03/00967 (filed 11/14/2003). This application claims benefit from foreign patent application (CHINA) 02149375.8 (filed 11/14/2002). The instant application has been granted the benefit date, 14 November 2002, from foreign patent application (CHINA) 02149375.8.

RESPONSE TO ARGUMENTS

35 USC § 102/103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Matsumoto

The rejection of claims 14 and 18-19 under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Matsumoto et al (US-6,010,722, issued 4 January 2000) is withdrawn in response to the applicants claim amendments. The applicant has cancelled claims 14 and 18-19. Therefore, the examiner hereby withdraws the rejection of claims 14 and 18-19 under 35 USC 102/103 over Matsumoto et al.

Vuorio, Young, Nah, Sandell1, Sandell2 and Upholt

The examiner withdraws the portion of the rejection of claim 13 under 35 USC 102/103 based upon an interpretation of the claim as being a dinucleotide, in response to the applicant's claim amendments.

However, claim 13 remains rejected under 35 U.S.C. 103(a) as unpatentable over Vuorio et al. (Nucleic Acids Research. 1982; 10:1175-1192) in view of Young et al. (Nucleic Acids Res. 1984; 12 (10), 4207-4228) in view of Nah et al. (Journal of Biological Chemistry. 1991; 266(34): 23446-23452) and further in view of Sandell et al. (Journal of Biological Chemistry. 1984; 259(12): 7826-7834) [known hereinafter as Sandell1] and further in view of Sandell et al. (Journal of Biological Chemistry. 1983; 258(19): 11617-11621) [known hereinafter as Sandell2] and further in view of Upholt et al. (PNAS. April 1986; Vol.83: 2325-2329) for the reasons below.

The applicant argues that the pending rejection "is believed to be no longer applicable in light of the amendment submitted to Claim 13" (Remarks, page 4, filed 8/17/2010).

In the action mailed 2/17/2010, the examiner stated:
"The cited references provided polynucleotide sequences for chicken type 2A1 collagen cDNA to the publicly available database, Genbank. All of the references are prior art to the instant application. Each of the references provide different portions of the cDNA sequence. Accordingly, the examiner views the cited art as obvious over instant claim 13."

and

"If the applicant decides that cited art has not provided for the full sequence of SEQ ID NO:2., the examiner respectfully requests a precise indication of the deficient region."

The applicant has not indicated which portion of SEQ ID NO:2 (chicken collagen 2 cDNA) was not taught by the cited art. Therefore, the examiner finds the applicant's argument and claim amendments unpersuasive.

The examiner reiterates the pending rejection:

Claim 13 is directed to an isolated polynucleotide comprising SEQ ID NO:2.

All of the cited references encode a portion of type II chicken collagen.

The specification further indicates that the full length type II chicken collagen cDNA is 4837bp and consists of an open reading frame (ORF) of 4260bp and a 3' nontranslated region of 520bp. The examiner notes that instant SEQ ID NO:2 is 4793bp. The specification inaccurately indicates that SEQ ID NO:2 is the mature chicken collagen II polypeptide (page 12, paragraphs 2-4). The examiner has provided a sequence alignment between the full length type II chicken collagen cDNA as provided by Genbank and instant SEQ ID NO:2. It is clear from the attached alignment

that SEQ IDNO:2 and the cDNA for chicken type 2A1 collagen are nearly identical. The differences being (1) SEQ ID NO:2 lacks 44 nucleotides at the 5' end of CCOL2A1 cDNA and (2) that SEQ ID NO:2 has a single nucleotide change which results in a single Threonine to Alanine amino acid mutation at amino acid 24. Both the specification and art indicate that the cDNA for chicken type 2A1 collagen encode a 1420 amino acid protein. Therefore, the differences between the lengths of SEQ ID NO:2 and the cDNA for chicken type 2A1 collagen and 4260bp needed to encode a 1420 protein is due to both 5' and 3' untranslated nucleotides.

Numerous artisans submitted sequence data providing sequence for the exons which comprise the cDNA sequence of chicken type 2A1 collagen. By the time the applicant submitted SEQ ID NO:2, all the nucleotides of this sequence were known, with the exception of the point mutation resulting in a T24A mutation within the collagen polypeptide. As the genomic and cDNA sequences submitted to GenBank by the applicant in association with subsequent publication of their work on molecular cloning, characterization and localization of chicken type II procollagen gene has not maintained this anomalous mutation, the examiner presumes that the specification contains a typographical error. In addition, instant SEQ ID NO:3, does not contain the T24A mutation. Therefore, the examiner is further persuaded that nucleotide 70 of SEQ ID NO:2 is a typographical error. In addition, the applicant is on record (see various 1.132 Declarations by Dr. Xi) that the earliest submission to Genbank of the polynucleotide sequences encoding type II chicken collagen contained sequence differences from the

final submission. The examiner presumes that instant SEQ ID NO:2 contains such a (typographical) error.

The cited references provided polynucleotide sequences for chicken type 2A1 collagen cDNA to the publicly available database, Genbank. All of the references are prior art to the instant application. Each of the references provide different portions of the cDNA sequence. Accordingly, the examiner views the cited art as obvious over instant claim 13.

If the applicant decides that cited art has not provided for the full sequence of SEQ ID NO:2., the examiner respectfully requests a precise indication of the deficient region. As far as the examiner can determine, all sequences taught in SEQ ID NO:2 were publicly available at the time of filing.

It would have been obvious to the person of ordinary skill in the art at the time of the invention was made to provide a cDNA sequence for type II chicken collagen.

The person of ordinary skill in the art would have been motivated to compile the existing sequence data into a full-length coding sequence for type II chicken collagen, because the art, having knowledge of the (commercial and scientific) value of this sequence would work towards providing a complete cDNA sequence. Many of the references cited reflect overlapping authorship, demonstrating the quest for this sequence.

An artisan would have expected success, because all the data was of record.

Therefore the sequence Vuorio in view of Young in view of Nah and further in view of Sandell1 and further in view of Sandell2 and further in view of Upholt would have been *prima facie* obvious over the sequence of the instant application.

Vuorio, Young, Nah, Sandell1, Sandell2, Upholt & Matsumoto

Claims 15-17 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Vuorio et al. (Nucleic Acids Research. 1982; 10:1175-1192) in view of Young et al. (Nucleic Acids Res. 1984; 12 (10), 4207-4228) in view of Nah et al. (Journal of Biological Chemistry. 1991; 266(34): 23446-23452) and further in view of Sandell et al. (Journal of Biological Chemistry. 1984; 259(12): 7826-7834) [known hereinafter as Sandell1] and further in view of Sandell et al. (Journal of Biological Chemistry. 1983; 258(19): 11617-11621)) [known hereinafter as Sandell2] and further in view of Upholt et al. (PNAS. April 1986; Vol.83: 2325-2329) as applied to claim 13 above, and further in view of Matsumoto et al (US-6,010,722, issued 4 January 2000) for the reasons of record and the comments below.

The applicant's arguments have been fully considered but are unpersuasive.

The applicant argues that as claims 15-17 depend from claim 13 and "none of the cited documents describe or suggest the cloning of a polynucleotide sequence as defined in claims 12 or 13" (Remarks, page 5), the rejection should be withdrawn. As described above, the sequence of claim 13 is obvious over the cited art. The applicant has failed to provide a specific portion of the sequence which is not taught by the cited references. Accordingly, the examiner finds the applicant's argument unpersuasive.

Therefore, the examiner hereby maintains the rejection of claims 15-17 under 35 U.S.C. 103(a) as being unpatentable over Vuorio et al. (Nucleic Acids Research. 1982; 10:1175-1192) in view of Young et al. (Nucleic Acids Res. 1984; 12 (10), 4207-4228) in view of Nah et al. (Journal of Biological Chemistry. 1991; 266(34): 23446-23452) and further in view of Sandell et al. (Journal of Biological Chemistry. 1984; 259(12): 7826-7834) [known hereinafter as Sandell1] and further in view of Sandell et al. (Journal of Biological Chemistry. 1983; 258(19): 11617-11621)) [known hereinafter as Sandell2] and further in view of Upholt et al. (PNAS. April 1986; Vol.83: 2325-2329) as applied to claim 13 above, and further in view of Matsumoto et al (US-6,010,722, issued 4 January 2000)

The examiner reiterates the pending rejection:

Claims 15-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vuorio et al. (Nucleic Acids Research. 1982; 10:1175-1192) in view of Young et al. (Nucleic Acids Res. 1984; 12 (10), 4207-4228) in view of Nah et al. (Journal of Biological Chemistry. 1991; 266(34): 23446-23452) and further in view of Sandell et al. (Journal of Biological Chemistry. 1984; 259(12): 7826-7834) [known hereinafter as Sandell1] and further in view of Sandell et al. (Journal of Biological Chemistry. 1983; 258(19): 11617-11621)) [known hereinafter as Sandell2] and further in view of Upholt et al. (PNAS. April 1986; Vol.83: 2325-2329) as applied to claim 13 above, and further in view of Matsumoto et al (US-6,010,722, issued 4 January 2000).

The teachings of Vuorio, Young, Nah, Sandell1, Sandell2, and Upholt are described above in a previous 35 USC 103(a) rejection. These references provide the

polynucleotide sequence for type II chicken collagen cDNA. SEQ ID NO:2 is a polynucleotide sequence for type II chicken collagen cDNA.

Furthermore, as the examiner can interpret "producing a chicken type II collagen" as producing a fragment of chicken type II collagen, the examiner can apply each of Vuorio, Young, Nah, Sandell1, Sandell2, and Upholt as providing the necessary polynucleotide sequences to produce "a chicken type II collagen."

Matsumoto teach methods of producing recombinant type II chicken collage using recombinant host cells comprising expression vectors comprising a polynucleotide sequence for type II chicken collagen cDNA. These teachings correspond to instant claims 15-17.

It would have been obvious to the person of ordinary skill in the art at the time of the invention was made to produce recombinant type II chicken collagen using recombinant host cells comprising expression vectors comprising a polynucleotide sequence for type II chicken collagen cDNA.

The person of ordinary skill in the art would have been motivated to produce recombinant type II chicken collagen, because Matsumoto recognized the commercial and scientific value of this molecule as a food and drug.

An artisan would have expected success, because all the data and methods are of record and practiced by skilled artisans

Therefore the expression vectors, recombinant host cells and methods of making recombinant type II chicken collagen as taught by Vuorio in view of Young in view of Nah and further in view of Sandell1 and further in view of Sandell2 and further in view of

Uphold and further in view of Matsumoto would have been *prima facie* obvious over the products and methods of the instant application.

35 USC § 112, 1st (Enablement)

The rejection of claim 17 under 35 USC 112, 1st paragraph (lack of enablement) is withdrawn in response to the applicants claim amendments. The applicant's claim amendments have been fully considered and are persuasive. The applicant has amended claim 17 to recite merely a method for expression of an unknown recombinant proteins. The claims no longer recite a method for producing recombinant chicken collagen. Producing an unknown protein by recombinant means is enabled. Therefore, the examiner hereby withdraws the rejection of claim 17 under 35 USC 112, 1st paragraph (lack of enablement)

35 USC § 112, 2nd

The rejection of claim 14 under 35 USC 112, second paragraph, as failing to set forth the subject matter which applicant(s) regard as their invention is withdrawn in response to the applicants claim amendments. The applicant's claim amendments have been fully considered and are persuasive. The applicant has amended claim 17 to recite merely a method for expression of an unknown recombinant proteins. The claims no longer recite a method for producing recombinant chicken collagen. Producing an unknown protein by recombinant means is enabled. Therefore, the examiner hereby withdraws the rejection of claim 14 under 35 USC 112, 2nd paragraph.

35 USC § 101 and § 112 (Lack of Utility)

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 12, 15 and 16 remain rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons of record and the comments below.

The applicant's arguments have been fully considered but are unpersuasive.

The applicant has provided 13 pages of arguments (Remarks, pages 5-18), but within those pages, the examiner has been unable to find any argument addressing the main point of the pending rejection, namely, that SEQ ID NO:1 does not seem to encode a known protein. Claim 12 is directed to an isolated polynucleotide comprising SEQ ID NO:1. The applicant's arguments are directed to the utility of chicken collagen. The applicant will notice that the examiner has not rejected claim 13 under 35 USC 101. Accordingly, the portion of claims 15-16 which lack utility are those which require the sequence of claim 12 (namely SEQ ID NO:1). As the applicant has failed to provide a substantial utility for or an indication of the identity of SEQ ID NO:1, the examiner finds the applicant's arguments unpersuasive.

Therefore, the examiner hereby maintains the rejection of claims 12, 15 and 16 under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

The examiner reiterates the pending rejection:

Claim 12, 15 and 16 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

When determining whether an applicant has described the utility of invention, one has to determine whether the claimed invention has a well-established utility. If not, it must be established that the application has made an assertion of specific, substantial and credible utility. A credible utility is assessed from the standpoint of whether a person of ordinary skill in the art would accept that the recited or disclosed invention is currently available for use. In contrast to general utility, a specific utility will be specific to the claimed subject matter. A substantial utility defines a real world utility of the invention, while utilities that require or constitute carrying out further research to identify or reasonably confirm a real world context or use are not considered substantial utility (see utility guidelines, in Federal Register 5 January 2001, Volume 6, Number 5, Pages 1092-1099).

The specification teaches that the present invention relates to the discovery, identification and characterization of a novel polynucleotide, SEQ ID NO:1 that encodes type II chicken collagen. However, SEQ ID NO:1 does NOT encode type II chicken collagen. The examiner has included a sequence alignment between the Genbank

protein sequence for Chicken Collagen, type 2A1 and 5'-3' translations of SEQ ID NO:1 for each of the three frames. It is clear that SEQ ID NO:1 does not encode chicken collagen, type 2A1, as suggested by the specification.

A novel nucleic acid sequence has no utility. The specification does not disclose the function of SEQ ID NO:1. Without such knowledge, one would not know how to use the polynucleotide and the encoded protein for a real world utility.

The applicant is referred to the Revised Utility Examination Guidelines published December 21, 1999 in the Federal Register, Volume 64, Number 244, pages 71441-71442 for the required *specific and substantial* utility. "A CLAIMED INVENTION MUST HAVE A SPECIFIC AND SUBSTANTIAL UTILITY. THIS REQUIREMENT EXCLUDES 'THROW-AWAY,' 'UNSUBSTANTIAL,' OR 'NONSPECIFIC' UTILITIES," (column 3, 3rd paragraph of 71441). According to the guidelines, utilities that require or constitute carrying further research to identify or reasonably confirm a "real world" context of use are not *substantial* utilities.

Furthermore, the disclosed vectors and host cells are only useful for the production of more polynucleotide or of polypeptides encoded thereby, and for further research. These utilities apply to many unrelated human polynucleotide fragments and are not considered a specific and substantial utility in those instances where the final product, has no disclosed or well-established utility.

In view of the instant specification, the only readily apparent *immediate* utility for the disclosed polynucleotide is characterization of the polynucleotide itself in terms of map location, possibility of association with a disease gene, sequence of corresponding mRNA, cDNA, and polypeptide, identity of the function for the corresponding

polypeptide and variants, etc. The sole immediate utility constitutes research on the claimed product itself (which is a non-statutory utility) in order to determine a specific and substantial statutory utility for the claimed invention. Practice of these disclosed utilities would first require further research on the disclosed sequence itself, i.e. there is no apparent immediate benefit to the public. *Brenner v. Manson*, 148 USPQ 689, 696 (US SupCt, 1966) noted that "CONGRESS INTENDED THAT NO PATENT BE GRANTED ON A CHEMICAL COMPOUND WHOSE SOLE 'UTILITY' CONSISTS OF ITS POTENTIAL ROLE AS AN OBJECT OF USE-TESTING", and stated, in context of the utility requirement, that "A PATENT IS NOT A HUNTING LICENSE. IT IS NOT A REWARD FOR THE SEARCH, BUT A COMPENSATION FOR ITS SUCCESSFUL CONCLUSION."

Because the claimed invention is not supported by a specific and substantial asserted utility or a well-established utility for the reasons set forth above, credibility of the asserted utility cannot be assessed.

Claims 12, 15 and 16 are also remain rejected under 35 U.S.C. 112, first paragraph for the reasons of record, the applicant having not provided any arguments directed to the unknown identity of SEQ ID NO:1. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Therefore, given the lack of guidance and direction in regard to what the polynucleotides would do and how one would use such, the artisan would be required to exercise undue experimentation in practice of the invention.

Specifically regarding the polypeptide molecule encoded by SEQ ID NO:1, it is not clear what the function of this molecule is or that it has shared functions with members of the collagen family. Since the function of the polypeptide molecule encoded by SEQ ID NO:1 is not understood, it is difficult to conclude that the polypeptide molecule encoded by SEQ ID NO:1 has a shared function with members of the collagen family or that the function has been disclosed in the instant application.

Therefore, in view of the limited guidance, the lack of predictability of the art and the breadth of the claims, one skilled in the art could not practice the invention without undue experimentation as it is broadly claimed.

NEW GROUNDS OF REJECTION

35 USC § 101 and § 112 (Lack of Utility)

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 17 is rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

When determining whether an applicant has described the utility of invention, one has to determine whether the claimed invention has a well-established utility. If not, it must be established that the application has made an assertion of specific, substantial and credible utility. A credible utility is assessed from the standpoint of whether a person of ordinary skill in the art would accept that the recited or disclosed invention is currently available for use. In contrast to general utility, a specific utility will be specific to the claimed subject matter. A substantial utility defines a real world utility of the invention, while utilities that require or constitute carrying out further research to identify or reasonably confirm a real world context or use are not considered substantial utility (see utility guidelines, in Federal Register 5 January 2001, Volume 6, Number 5, Pages 1092-1099).

The specification teaches that the present invention relates to the discovery, identification and characterization of a novel polynucleotide, SEQ ID NO:1 that encodes type II chicken collagen. However, SEQ ID NO:1 does NOT encode type II chicken collagen. With the Action (mailed 2/17/2010), the examiner has included a sequence alignment between the Genbank protein sequence for Chicken Collagen, type 2A1 and 5'-3' translations of SEQ ID NO:1 for each of the three frames. It is clear that SEQ ID NO:1 does not encode chicken collagen, type 2A1, as suggested by the specification.

A novel nucleic acid sequence has no utility. The specification does not disclose the function of SEQ ID NO:1. Without such knowledge, one would not know how to use the polynucleotide and the encoded protein for a real world utility. Accordingly, a

method of making a recombinant protein encoded by SEQ ID NO:1 would have no utility.

The applicant is referred to the Revised Utility Examination Guidelines published December 21, 1999 in the Federal Register, Volume 64, Number 244, pages 71441-71442 for the required *specific and substantial* utility. "A CLAIMED INVENTION MUST HAVE A SPECIFIC AND SUBSTANTIAL UTILITY. THIS REQUIREMENT EXCLUDES 'THROW-AWAY,' 'UNSUBSTANTIAL,' OR 'NONSPECIFIC' UTILITIES," (column 3, 3rd paragraph of 71441). According to the guidelines, utilities that require or constitute carrying further research to identify or reasonably confirm a "real world" context of use are not *substantial* utilities.

Furthermore, the disclosed vectors and host cells are only useful for the production of more polynucleotide or of polypeptides encoded thereby, and for further research. These utilities apply to many unrelated human polynucleotide fragments and are not considered a specific and substantial utility in those instances where the final product, has no disclosed or well-established utility.

In view of the instant specification, the only readily apparent *immediate* utility for the disclosed polynucleotide is characterization of the polynucleotide itself in terms of map location, possibility of association with a disease gene, sequence of corresponding mRNA, cDNA, and polypeptide, identity of the function for the corresponding polypeptide and variants, etc. The sole immediate utility constitutes research on the claimed product itself (which is a non-statutory utility) in order to determine a specific and substantial statutory utility for the claimed invention. Practice of these disclosed utilities would first require further research on the disclosed sequence itself, i.e. there is

no apparent immediate benefit to the public. Brenner v. Manson, 148 USPQ 689, 696 (US SupCt, 1966) noted that "CONGRESS INTENDED THAT NO PATENT BE GRANTED ON A CHEMICAL COMPOUND WHOSE SOLE 'UTILITY' CONSISTS OF ITS POTENTIAL ROLE AS AN OBJECT OF USE-TESTING", and stated, in context of the utility requirement, that "A PATENT IS NOT A HUNTING LICENSE. IT IS NOT A REWARD FOR THE SEARCH, BUT A COMPENSATION FOR ITS SUCCESSFUL CONCLUSION."

Because the claimed invention is not supported by a specific and substantial asserted utility or a well-established utility for the reasons set forth above, credibility of the asserted utility cannot be assessed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

No claims are allowed.

Examiner Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Scott Long** whose telephone number is **571-272-9048**. The examiner can normally be reached on Monday - Friday, 9am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Joseph Woitach** can be reached on **571-272-0739**. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/SCOTT LONG/
Primary Examiner, Art Unit 1633